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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/700,018	11/03/2003	Paul M. Lizardi	25006.0003U4	4956

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EXAMINER	
TUNG, JOYCE	
ART UNIT	**PAPER NUMBER**
1637	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/700,018	LIZARDI, PAUL M.	
	Examiner	Art Unit	
	Joyce Tung	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *32,34-44 and 46-50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *32, 34-44, 46-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The applicant's response filed 5/14/07 to the Office action has been entered. Claims 32, 34-44 and 46-50 are pending.

1. Applicant's arguments with respect to claims 32, 34-44 and 46-50 have been considered but are moot in view of the new ground(s) of rejection.

NEW GROUND OF REJECTIONS

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 34, 39-44 and 47-48 are rejected under 35 U.S.C. 102(e) as being anticipated by Lupski et al. (5,691,136, issued Nov. 1997).

Lupski et al. disclose oligonucleotide primers and a method for identifying strains of bacteria in a sample (See column 2, lines 27-30). The primers are about 10-29 nucleotide bases in length and preferably between about 15-25 bases in length (See column 3, lines 12-15). Each primer pair is selected to be substantially complementary to the different strands of each specific repetitive sequence to which the primer pairs bind (See column 5, lines 15-22). The sample contains a plurality of strains of bacteria (See column 6, lines 14-16, column 51, lines 65-67). The polymerases used in the method are *Taq* DNA polymerase, *E. coli* DNA polymerase I and Klenow fragment of *E. coli* DNA polymerase I and Vent DNA polymerase (See column 7, lines 17-24). The invention also

includes a kit for the method containing a pair of PCR primers to a repetitive sequence in bacteria (See column 9, lines 29-33).

Lupski et al. do not explicitly disclose that each primer has a constant portion and a random portion.

In fig. 3, there are four primers in a right set and a left set. These sequences are the alignment of ERIC oligonucleotide primer sequences with respect to the central inverted repeat of an ERIC consensus sequence (See column 3, lines 51-54). This teaching is inherent that all of the primers in the set of primers are complementary to the same strand of the target sequence as recited in claim 47. These primers are all of the same length (See fig. 3). There are four primers for a right set and a left set (See fig. 3) and the right set and left set of primers each has the same number of primers (See fig.3). The primers have a constant portion, TT, GGG, and AA and a random portion comprises ATCG (See fig. 3). The constant portion of each primer is the same (See fig. 3). Thus, the teachings of Lupski et al. are inherent that each primer has a constant portion and a random portion and the constant portion of each primer are the same.

Lupski et al. also do not disclose strand displacement factor compatible with DNA polymerase.

New England BioLabs disclose that Klenow fragment of *E. coli* DNA polymerase I has strand displacement activity (See attached New England BioLabs catalogue pages). It is inherent that the polymerase used by Lupski et al. has strand displacement activity.

Based upon the analysis above, the teachings of Lupski et al. anticipate the limitations of the claims.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 32, 35-37 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lupski et al. (5,691,136, issued Nov. 1997).

Lupski et al. disclose oligonucleotide primers and a method for identifying strains of bacteria in a sample (See column 2, lines 27-30). The primers are about 10-29 nucleotide bases in length and preferably between about 15-25 bases in length (See column 3, lines 12-15). The method applies multiple primers to different repetitive DNA (See column 3, lines 30-34). Each primer pair is selected to be substantially complementary to the different strands of each specific repetitive sequence to which the primer pairs bind (See column 5, lines 15-22). The polymerases used in the method are *Taq* DNA polymerase, *E. coli* DNA polymerase I and Klenow fragment of *E. coli* DNA

polymerase I and Vent DNA polymerase (See column 7, lines 17-24). The invention also includes a kit for the method containing a pair of PCR primers to a repetitive sequence in bacteria (See column 9, lines 29-33). The kit can have any of the PCR primers as disclosed by the invention (See column 9, lines 33-35). One skilled in the art will readily recognize that the number and type of primers, which are in the kit, will depend on the use of the kit as well as the sequences, which are to be detected (See column 9, lines 36-39). The sample contains a plurality of strains of bacteria (See column 51, lines 65-67).

Lupski et al. also do not disclose strand displacement factor compatible with DNA polymerase.

New England BioLabs disclose that Klenow fragment of *E. coli* DNA polymerase I has strand displacement activity (See attached New England BioLabs catalogue pages). It is inherent that the polymerase used by Lupski et al. has strand displacement activity.

Lupski et al. do not disclose that the kit contains 4 or more primers, which are respectively in a right set of primers, and a left set of primers.

In fig. 3, there are four primers in a right set and a left set. These sequences are the alignment of ERIC oligonucleotide primer sequences with respect to the central inverted repeat of an ERIC consensus sequence (See column 3, lines 51-54). These primers are all of the same length (See fig. 3). There are four primers for a right set and a left set (See fig. 3) and the right set and left set of primers each has the same number of primers (See fig.3). As indicated by Lupski et al., one skilled in the art will readily recognize that the number and type of primers, which are in the kit, will depend on the use of the kit as well as the sequences, which are to be detected (See column 9, lines 36-39).

Thus one of ordinary skill in the art would have been motivated to make the kit with four or more primer in a right set primer and a left set primer because of the suggestion of Lupski et al. (See column 9, lines 36-39). It would have been prima facie obvious to make the kit with four or more primers, which are respectively in a right set and a left set.

6. Claims 38, 46, and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lupski et al. (5,691,136, issued Nov. 1997) as applied to claims 32, 34-37, 39-44 and 47-49 further in view of Blanco et al. (Journal of Biological Chemistry, 1989, Vol. 264(15), pg. 8935-40).

Lupski et al. do not disclose that the kit contains phage vphi 29 DNA polymerase for strand displacement activity.

Blanco et al. disclose that phage vphi 29 DNA polymerase is highly processive in the absence of any accessory protein and is able to produce strand displacement coupled to the polymerization process (See the Abstract).

One of ordinary skill in the art would have been motivated to include phage vphi 29 DNA polymerase in the kit for amplifying a target nucleic acid as claimed because of the benefit of using the vphi29 DNA polymerase. It would have been prima facie obvious to include phage vphi 29 DNA polymerase in the kit for performing the amplification of the target nucleic acid.

Summary

7. No claims are allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (571) 272-0790. The examiner can normally be reached on Monday - Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Joyce Tung
August 2, 2007

KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER
8/6/07